Bioway Chemistry Reagent Series
Albumin Test Kit

Detection of Albumin in Human Serum or Plasma on Chemistry Analyzers

Cat. No. R004K11 ALB Reagent Kit

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

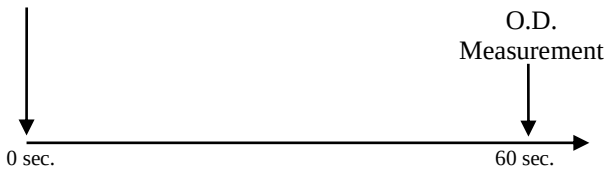

Table 1: Instrument Parameters*

Calibration method	2-point Linear	Slope of reaction	Increase
Testing wavelength	D λ: 630 nm Sλ : 700 nm	Sample volume	3 µl
Test method	1 point end	R1 volume	300 µl
Reaction temperature	37℃		

*Refer to Figure 1 and the package insert for detail

INTENDED USE

***Bioway Chemistry Reagent Series* ALB Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of Albumin in human serum or plasma on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Serum albumin is the major parts of the albumins which is a complex of variety of water-soluble proteins. It is produced by liver and plays an important role on maintaining plasma osmolality. Abnormal concentration of serum albumin may be found on the patients with ascites, malaria, leprosy, lupus, scleroderma, rheumatic fever, rheumatoid arthritis, cirrhosis of the liver or malnutrition.

TEST PRINCIPLES

The Kit utilizes bromocresol green method to measure the amount of ALB (g/L) in human serum or plasma.

Albumin + Bromocresol green $\xrightarrow{\text{acidic condition}}$ Green chromogen

Albumin reacts with bromocresol green and from a green colored complex. The increase in absorbance at 630 nm is directly proportional to the ALB concentration in the sample.

MATERIALS PROVIDED

Reagents:

R	Bromocresol green	0.15 g/L
	Succinate buffer, pH 4.2	75 mmol/L
	Brij-35	1.2 g/L
	Sodium azide	0.1 g/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer
2. ALB control and calibrator set (commercially available)

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. The reagent is stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum preventing hemolysis.

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at 2~8℃ for 7 days.

TEST PROCEDURE (see Figure 1)

Reagent 1 is liquid stable ready-to-use, no preparation needed.

Calibration: Recommend using commercially available calibrator set for optimal results.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 3 µl of sample and 300 µl of R1; mix well and incubate at 37℃ for 1 minute.
2. Take optical density measurement.
3. Calculate average Δ A

RESULT

The amount of ALB in g/L can be obtained by the following calculation:

$$\text{ALB (g/L)} = \frac{\Delta A\text{test}}{\Delta A\text{standard}} \times \text{standard solution (g/L)}$$

Please refer to instrument application if testing under different conditions.

EXPECTED VALUES

4~14y children 38~54 g/L
Adult 34~48 g/L

It is recommended for each laboratory to establish its own expected values

QALBLITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

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1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with ALB exceeding the maximum measurement range should be diluted with saline and retested.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 60 g/L (R≥0.990)

Accuracy: Bias proportion 90%~110%

Precision: Within Run: CV≤4%;
Run-to-Run: CV≤6%

Reagent Blank Absorbance: at 630nm wavelength and 10 mm optical diameter, O.D. ≤ 0.50

REFERENCES

1. Basil T. Doumas *et al.*, Clinica Chimica Acta**,** 31(1):87–96 (1971)
2. G. Tibbling *et al.*, Scandinavian Journal of Clinical & Laboratory Investigation, 37(5):385-390 (1977)
3. Rodkey F. L. *et al.*, Clin. Chem., 2:478 (1965)

Not Intended for Sale in the United States.

Pointe Biotech (Nanjing) Co., Ltd.

No.85,Xingmin South Road, Jiang Ning District, Nanjing,P.R.China 211100
Tel:86-25-52425019,
Fax:86-25-52424836
info@biowaydx.com